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JUN 1 1 2013

510(k) Summary: Mammomat Inspiration PRIME

Company: Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: June 11, 2013

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. General Information:

Importer / Distributor:
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355
Establishment Registration Number:
2240869
Manufacturing Site:
SIEMENS AG Sector Healthcare
Henkestraße 127
91050 Erlangen
Establishment Registration Number:
3004977335

2. Contact Person:
Ms. Patricia D Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway D-02
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

3. Device Name and Classification:

Trade Name:	Mammomat Inspiration PRIME
Device:	Full Field Digital, system, X-Ray Mammographic
Regulation:	Medical Specialty Radiology
Review Panel	Radiology
Product Code	MUE
Submission Type	510(k)
Regulation Number	892.1715
Device Class	2

4. Legally Marketed Predicate Device

Trade Name:	Mammomat Inspiration VB30
Device:	Full Field Digital, system, X-Ray Mammographic
Regulation:	Medical Specialty Radiology

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Review Panel	Radiology
Product Code	MUE
Submission Type	510(k)
Regulation Number	892.1715
Device Class	2

5. **Device Description:**
Mammomat Inspiration PRIME is a floor-mounted mammography system for screening, diagnostic and biopsy procedures on standing, seated or recumbent patients.

The Mammomat Inspiration PRIME provides optional gridless acquisition and progressive reconstruction. During progressive reconstruction a unique algorithm replicates the function of the grid. The grid slides back and no longer absorbs primary radiation, therefore less radiation dose is needed. The Mammomat Inspiration PRIME in gridless acquisition mode reduces radiation dose up to 30 percent.

The system consists of an examination stand with integrated, microprocessor-controlled, high-frequency generator as well as a radiation shield with an optional height-adjustable control desk in which the Acquisition Workstation (AWS) can be integrated. A swivel arm contains the X-ray tube on the top end and the object table with the detector on the bottom end.

6. **Indication for Use:**
The MAMMOMAT Inspiration PRIME system is intended for mammography exams, screening, diagnosis, and stereotactic biopsies under the supervision of medical professionals.

Mammographic images can be interpreted by either hard copy film or soft copy workstation.

7. **Substantial Equivalence:**
The Siemens Mammomat Inspiration PRIME is substantially equivalent to the commercially available Siemens Mammomat Inspiration P030010/S006.

X-ray generation and control used with the Mammomat Inspiration PRIME is identical to the Mammomat Inspiration with VB30. Detector TFT specifications and general image processing algorithms remain unchanged. The Acquisition Workstation (AWS) is identical.

8. **Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:**
The modified Mammomat Inspiration Prime can lower dose up to 30 percent compared to the predicate (P030010/S006) with equivalent image quality as evaluated with phantom testing and clinical image review. The dose can be reduced as the scatter radiation grid, which has been commonplace up to now, is replaced by a new algorithm for progressive image reconstruction. The conventional scatter radiation grid absorbs scattered radiation to ensure image quality. But as it also absorbs part of the important primary radiation, higher dose is needed to obtain images of the desired quality. The new algorithm can identify the scatter-causing

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structures and can calculate a corrected image. Thus, the primary radiation can be completely used and high-quality images can be achieved with less dose.

9. **Summary of Non-Clinical Tests:**
The Siemens Mammomat Inspiration Prime complies with voluntary standards as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the system:
- Risk Analysis
- Requirements Reviews
- Design Reviews
- Integration testing (System verification)
- Performance testing (Bench testing)

10 **Summary of Clinical Tests:**
For the subject of this premarket submission, Siemens Mammomat Inspiration Prime, included clinical testing to quantify the potential of dose savings. This clinical is described in Section 15 of this premarket submission.

11. **General Safety and Effectiveness Concerns:**
Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design. In addition the Mammomat Inspiration is continually monitored, and if an error occurs, the system functions will be blocked and an error message will be displayed.

Furthermore the operators are health care professionals familiar with and responsible for the X-ray examinations to be performed. To minimize electrical, mechanical and radiation hazards, Siemens adheres to recognized and established industry practice, and all equipment is subject to final performance testing.

12. **Conclusion as to Substantial Equivalence:**
The Mammomat Inspiration PRIME is intended for the same indications for use as the predicate Mammomat Inspiration VB30. The imaging properties (TFT with pixel size and number and image processing algorithms) have not been modified. It is Siemens opinion, that the Mammomat Inspiration PRIME is substantially equivalent to the Mammomat Inspiration P030010/S006.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 11, 2013

Ms. Patricia D. Jones
Siemens Medical Solution, Inc.
Technical Specialist, Regulatory Submissions
51 Valley Stream Parkway, E-50
MALVERN PA 19355

Re: K123520
Trade/Device Name: Mammomat Inspiration PRIME
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: May 31, 2013
Received: June 4, 2013

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123520

Device Name: Mammomat Inspiration PRIME

Indications for Use:

The Mammomat Inspiration system is intended for mammography exams, screening, diagnosis, and stereotactic biopsies under supervision of medical professionals.

Mammographic images can be interpreted by either hardcopy film or softcopy workstation.

Prescription Use _X_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

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